

## Nuclear Regulatory Commission

## § 26.717

or other entity shall retain documentation certifying the scientific and technical suitability of the assays and cutoff levels used, as required under § 26.31(d)(1)(i) and (d)(3)(iii)(C), respectively, for the time the FFD program follows these practices or until the completion of all related legal proceedings, whichever is later.

### **§ 26.715 Recordkeeping requirements for collection sites, licensee testing facilities, and laboratories certified by the Department of Health and Human Services.**

(a) Collection sites providing services to licensees and other entities who are subject to this subpart, licensee testing facilities, and HHS-certified laboratories shall maintain and make available documentation of all aspects of the testing process for at least 2 years or until the completion of all legal proceedings related to a determination of an FFD violation, whichever is later. This 2-year period may be extended on written notification by the NRC or by any licensee or other entity for whom services are being provided.

(b) Documentation that must be retained includes, but is not limited to, the following:

(1) Personnel files, including training records, for all individuals who have been authorized to have access to specimens, but are no longer under contract to or employed by the collection site, licensee testing facility, or HHS-certified laboratory;

(2) Chain-of-custody documents (other than forms recording specimens with negative test results and no FFD violations or anomalies, which may be destroyed after appropriate summary information has been recorded for program administration purposes);

(3) Quality assurance and quality control records;

(4) Superseded procedures;

(5) All test data (including calibration curves and any calculations used in determining test results);

(6) Test reports;

(7) Records pertaining to performance testing;

(8) Records pertaining to the investigation of testing errors or unsatisfactory performance discovered in quality control or blind performance testing, in the testing of actual specimens, or

through the processing of appeals and MRO reviews, as well as any other errors or matters that could adversely reflect on the integrity of the testing process, investigation findings, and corrective actions taken, where applicable;

(9) Performance records on certification inspections;

(10) Records of preventative maintenance on licensee testing facility instruments;

(11) Records that summarize any test results that the MRO determined to be scientifically insufficient for further action;

(12) Either printed or electronic copies of computer-generated data;

(13) Records that document the dates, times of entry and exit, escorts, and purposes of entry of authorized visitors, maintenance personnel, and service personnel who have accessed secured areas of licensee testing facilities and HHS-certified laboratories; and

(14) Records of the inspection, maintenance, and calibration of EBTs.

### **§ 26.717 Fitness-for-duty program performance data.**

(a) Licensees and other entities shall collect and compile FFD program performance data for each FFD program that is subject to this subpart.

(b) The FFD program performance data must include the following information:

(1) The random testing rate;

(2) Drugs for which testing is conducted and cutoff levels, including results of tests using lower cutoff levels, tests for drugs not included in the HHS panel, and any special analyses of dilute specimens permitted under § 26.163(a)(2);

(3) Populations tested (*i.e.*, individuals in applicant status, permanent licensee employees, C/Vs);

(4) Number of tests administered and results of those tests sorted by population tested (*i.e.*, individuals in applicant status, permanent licensee employees, C/Vs);

(5) Conditions under which the tests were performed, as defined in § 26.31(c);

(6) Substances identified;

(7) Number of subversion attempts by type;